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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/716,356	11/21/2000	Shimpei Ushio	USHIO-2	8174

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EXAMINER

LUCAS, ZACHARIAH

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 10/22/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/716,356

Applicant(s)

USHIO ET AL.

Examiner

Zachariah Lucas

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 October 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-94 is/are pending in the application.
- 4a) Of the above claim(s) 10-17 and 62-94 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 18-61 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☒ Certified copies of the priority documents have been received in Application No. see action.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Priority*

1. Acknowledgment is made of applicant's claim for foreign priority under 35

U.S.C. 119(a)-(d) to Japanese applications 304203/1994 and 262062/1995. The certified copies have been filed in parent Application No. 08/558,191, filed on November 15, 1995.

2. Acknowledgment is made of applicant's claim for foreign priority under 35

U.S.C. 119(a)-(d) to Japanese applications 78357/1995 and 274988/1995. The certified copies have been filed in parent Application No. 08/558,190, filed on March 20, 1996. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d) to Japanese application 58240/1995. The certified copy has been filed in parent Application No. 08/558,818, filed on March 21, 1996. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d) to Japanese applications 270725/1995, 67434/1996, and 269105/1996. The certified copies have been filed in parent Application No. 08/721,018, filed on November 15, 1995. *Information Disclosure Statement*

5. The information disclosure statement filed November 21, 2000 fails, in part, to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. The Maramatsu reference, listed as reference BF in the IDS, is in a foreign language, with no abstract or other indication of the relevance of the reference provided other than that it is a laboratory Manual. The Toyama reference, identified as reference As in the IDS, was found in priority

Art Unit: 1648

application 08/558,818, however, this reference also was present only in a foreign language, with no translation or abstract in English. The information referred to therein has not been considered.

6. The information disclosure statement filed November 21, 2000 fails, in part, to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. The examiner located the Blakwill reference, identified as reference BC in the IDS, and an excerpt from the Hatt reference in parent application 08/721,018.

However, the applicant provided only the Foreword and table of contents of the Blakwill reference, and the title page and page 178 of the Hatt reference. The references have therefore been examined only to the extent of the material provided.

7. The following references were not found in the USPTO files: XP-002024314 (reference AN), Tijssen (reference AT), and Japan Abstract 05279376 (reference BG). It would be appreciated if the applicant would provide new copies to forward prosecution in the case.

#### ***Election/Restrictions***

8. Claims 10-17, 62-79, and 92-94 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 11.

Art Unit: 1648

9. Claims 80-91 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in Paper No. 11.

10. Applicant's election with traverse of Group I in Paper No. 11 is acknowledged. The traversal is on the ground(s) that it would not be an undue burden on the examiner to examine all of the claimed inventions. This is not found persuasive because each of the inventions requires search strategies and search of fields not required for the other inventions.

With regards to the restriction between the Groups I-III, the applicant further argues that burden has not been shown in the present case because each of these Groups were examined together in the parent case. This is also not found persuasive. In part, this is because the restriction among inventions is, within the limits set by the MPEP, 37 CFR, and other law surrounding patent practice and procedure, a matter of discretion that lies with the examiner. The fact that the examiner who handled the parent case chose not to restrict is not dispositive of the propriety of a restriction requirement made in a later case. The examiner would also note that in the parent case, the claims were limited to the polypeptide and the DNA. Such is not the case in the present case. In the case currently under consideration, the claims read on not only the peptide itself, but to compositions including the polypeptide. Thus, the examination of the peptide is no longer limited to the peptide sequence itself, thereby increasing the burden of the examination on the examiner. In this application, it was felt that the extra burden represented by the composition claims justified the restriction requirement.

The requirement is still deemed proper and is therefore made FINAL.

Art Unit: 1648

### ***Double Patenting***

11. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

12. Claim 3 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 29 of prior U.S. Patent No. 6,214,584. This is a statutory double patenting rejection.

13. Claims 53, 54, 55, 57, 58, 56, 59, 60, and 61 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 1-9 of prior U.S. Patent No. 6,207,641. For the purposes of this rejection, it is being assumed that the biological activity of subpart (d) of claim 53 is identical to the first subpart (d) of claim 1 of the patent. This is a double patenting rejection.

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Art Unit: 1648

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 1, 2, 4, and 5 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 27, 28, 30, and 31 of U.S. Patent No. 6,214,584 in view of claim 29 from that same patent. The conflicting claims are not identical because the claims corresponding to claims 1, 2, 4, and 5 in the patent do not require that the Xaa at position 73 (Xaa73) of the protein be an isoleucine or a threonine. However, the claims are not patentably distinct from each other because claim 29 of the patent makes it clear that the currently claimed inventions, limited to embodiments wherein Xaa73 is an Ile or a Thr, are encompassed by the other identified patent claims. Thus, the instant claims are obvious variations on the inventions claimed in U.S. Patent 6,214,584.

16. Claims 1-4, 6-9 and 18, 19, 21-55, 57-61 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,441,138, and likewise rejected over claims 1-3 of Patent 6,403,079. Although the conflicting claims are not identical, they are not patentably distinct from each other because the polypeptide claimed by the '138 is described as identical to the polypeptide currently claimed in claims 1-4 of the instant application. See, '138 patent, col. 3, lines 10-36. Further, the '138 patent teaches the combination of the claimed polypeptide with physiologically -acceptable carriers (presumably the same as pharmaceutically-acceptable carriers) and with the various other active ingredients of claims 6-9, 21-52, 57, 59, and 60. '138 Patent, col.6, lines 4-37. Further, the '138 patent also teaches the use of the polypeptide with the stabilizers of claims 54 and 61 in columns

Art Unit: 1648

15-16 of the patent. Finally, the patent teaches that composition may be used to induce activity of various killer cells such a NK, LAK, and cytotoxic T-cells. *Id.*, Col. 5, lines 32-60. The same teachings are also found in the '079 patent.

The above rejection is, in part, based on the specification of a previously issued patent, rather than the claims. In support of the use of this material, the examiner notes the following excerpt from MPEP section 804:

When considering whether the invention defined in a claim of an application is an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art. This does not mean that one is precluded from all use of the patent disclosure.

The specification can always be used as a dictionary to learn the meaning of a term in the patent claim. In *re Boylan*, 392 F.2d 1017, 157 USPQ 370 (CCPA 1968). Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. In *re Vogel*, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970). The court in *Vogel* recognized "that it is most difficult, if not meaningless, to try to say what is or is not an obvious variation of a claim," but that one can judge whether or not the invention claimed in an application is an obvious variation of an embodiment disclosed in the patent which provides support for the patent claim. According to the court, one must first "determine how much of the patent disclosure pertains to the invention claimed in the patent" because only "[t]his portion of the specification supports the patent claims and may be considered." The court pointed out that "this use of the disclosure is not in contravention of the cases forbidding its use as prior art, nor is it applying the patent as a reference under 35 U.S.C. 103, since only the disclosure of the invention claimed in the patent may be examined."

Thus, the courts have held that it is permissible to use the specification in determining what is included in, and obvious from, the invention defined by the claim on which the rejection is based. This is true even where elements are drawn from the specification describing the claimed invention, although the elements are not in the claim itself.

17. Claims 1-9, and 18-61 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,207,641.

Although the conflicting claims are not identical, they are not patentably distinct from each other



Art Unit: 1648

because the further elements of the claims in the instant application are taught by those portions of the patent specification relating to the pharmaceutical compositions claimed by the patent.

See, Patent, cols. 7-8. The same reasoning as used in the rejections based on U.S. Patent Nos. 6,441,138, and 6,403,079 also applies in this rejection.

### ***Claim Objections***

18. Claims 53, and its dependant claims 54-61, are objected to because of the following informalities: In the listing of the physiochemical properties of the polypeptide, the claim fails to specify the biological activity required (i.e. limitation (d) is incomplete). Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

19. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

20. Claims 18, 20, 21-52, 57, and 53-57 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition comprising SEQ ID NO: 6, or for derivatives thereof varying from SEQ ID NO: 6 by one amino acid residue, does not reasonably provide enablement for a composition comprising any homologue of the sequence. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. The claims read not only on compositions comprising the polypeptides of SEQ ID NO: 6,

Art Unit: 1648

but also to homologous sequences comprising one or more (at least one) substitutions or deletions within the sequence of SEQ ID NO: 6.

However, the specification identifies no such homologues. It also fails to identify what regions of the disclosed protein are active in inducing Interferon- $\gamma$  production. All that the specification does describe in relation to the homologues is that they may be made by substituting, adding, or deleting one or more amino acids in the protein of SEQ ID NO: 6. App., p. 9. This is obvious and unhelpful. It provides no guidance as to which of the many potential individual or combination of substitutions, additions, and deletions may provide functional homologues to the disclosed protein.

The specification also describes the preparation of polypeptides from several sources. However there is no showing that these polypeptides are homologues of, and not identical to, the polypeptide of SEQ ID NO: 6. See, App., pp. 74-81. Further, even if these are homologous peptides, without some guidance as to how these polypeptides vary from SEQ ID NO: 6, the examples do not provide sufficient guidance to allow one skilled in the art to make functional homologues. One skilled in the art has no guidance as to what homologous sequences would work as the specification has provided neither examples of homologous sequences, nor identification of sequences that such homologues would contain that would allow it to perform the indicated function.

The art recognizes that most proteins are amenable to substitutions or mutations of one or more residues within their amino acid sequences without losing functionality. See e.g., Bowie et al., Science, Vol. 247, 1306-1310. However, the art also recognizes that such amenability is greatly reduced where the residue in question is important to either the function or the structure

Art Unit: 1648

(due to the interconnection between the protein structures and function) of the protein. Id. Thus, in order for one of skill in the art to make functional homologues of a protein, such a person would need some guidance in the form of examples or an identification of an active region of the protein so as to know what residues will be likely to be less amenable to substitution or deletion. As the specification has provided no such guidance, the present claims to such homologues are more of an invitation to find the homologues than a demarcation of the applicant's invention.

21. Claims 18, 20, 21-52, 57, and 53-57 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are described above.

The following quotation from section 2163 of the Manual of Patent Examination Procedure is a brief discussion of what is required in a specification to satisfy the 35 U.S.C. 112 written description requirement for a generic claim covering several distinct inventions:

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice..., reduction to drawings..., or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus... See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

Also relevant to the discussion are the following excerpts from the case of *In re Borkowski and Van Venrooy*, 164 USPQ 642, (CCPA 1970). In describing the appropriate grounds for a claim rejection when the claim exceeds the scope of the disclosure, the court stated the following:

Art Unit: 1648

*... a specification need not contain a working example if the invention is otherwise disclosed in such a manner that one skilled in the art will be able to practice it without an undue amount of experimentation. (Excerpt from 164 U.S.P.Q. at 645)*

and;

*... if the "enabling" disclosure of a specification is not commensurate in scope with the subject matter encompassed by a claim, that fact does not render the claim imprecise or indefinite or otherwise not in compliance with the second paragraph of §112; rather, the claim is based on an insufficient disclosure 4 (§112, first paragraph) and should be rejected on that ground. See In re Fuetterer, 50 CCPA 1453, 319 F.2d 259, 138 USPQ 217 (1963); In re Kamal, 55 CCPA 1409, 398 F.2d 867, 158 USPQ 320 (1968); and In re Wakefield, 164 USPQ (PA 8192), decided concurrently herewith. Thus, just as a claim which is of such breadth that it reads on subject matter disclosed in the prior art is rejected under §102 rather than under the second paragraph of §112, a claim which is of such breadth that it reads on subject matter as to which the specification is not "enabling" should be rejected under the first paragraph of §112. (Excerpt from 164 U.S.P.Q. at 646).*

Thus, when a claim covers a genus of inventions the specification must provide written description support for the entire scope of the genus. Support for a genus is generally found where the applicant has provided a number of examples sufficient so that one in the art would recognize from the specification the scope of what is being claimed. However, a disclosure will also support the claims in the absence of examples if the description would enable one in the art to practice the invention without such guidance.

Although the claims in the present case are not put forth as generic claims to a genus of inventions, the fact that they are claiming not only SEQ ID NO: 6, but also all of its homologues, makes the claims generic to all such proteins. However, as in other situations where an applicant is claiming a genus of inventions, the present case also requires some description of a representative number of homologues such that one of ordinary skill in the art would recognize other members of the claimed genus. No such examples, other than SEQ ID NO: 6 itself, have been presented. As the applicant has not provided such a description so as to allow one in the art to recognize such homologues, the applicant has not provided a sufficient written description to support claims that read on them.

Art Unit: 1648

22. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

23. Claims 18, 20, 21-52, 57, and 53-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims read on embodiments of the claimed invention wherein the composition comprises a homologue of SEQ ID NO: 6 comprising at least one substitutions or deletions. As no definition as to what comprises a homologue SEQ ID NO: 6 is provided, the claims could read on any protein that induces the production of interferon- $\gamma$  so long as it shares the chemical properties as described in claim 18.

24. Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim reads on a pharmaceutical composition that comprises of SEQ ID NO: 6, or a biologically active fragment thereof. The claim is rejected because it is not clear what biological activity the fragment is required to have. It is suggested that the applicant incorporate the language from claim 18 which specifies that the fragment have the "same interferon- $\gamma$  inducing activity as the polypeptide of SEQ ID NO: 6.

25. Claims 53 and its dependant claims 54-61, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 53, and therefore its dependant claims, is

Art Unit: 1648

indefinite because, although it recites an intended use for the claimed composition, it recites that the polypeptide must have a biological activity, but fails to identify a biological activity for the polypeptide that it comprises (i.e. limitation (d) is incomplete). It is therefore not clear what biological activity the polypeptide itself is required to have.

***Claim Rejections - 35 USC § 102***

26. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

27. Claims 53, 56, 57, and 60 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Number 5,912,324, issued to Okamura et al. These claims read on homologues of SEQ ID NO: 6 having the properties of having a molecular weight of  $18,500 \pm 3,000$  daltons, an isoelectric point of  $4.9 \pm 1.0$  on chromatofocusing, and a biological activity. For the purposes of this rejection, the claim is being read as requiring the biological activity of inducing interferon- $\gamma$  production. Okamura also teaches an interferon- $\gamma$  inducing polypeptide. As is demonstrated by

Art Unit: 1648

claim 1 of the patent, the polypeptide disclosed therein has a similar molecular weight and isoelectric point with the currently claimed polypeptide. Further, in column 7 of the patent, the polypeptide is disclosed as being usable with interleukin-2 an/or with a tumor necrosis factor. Thus, the reference anticipates that stated claims.

This rejection does not conflict with the issuance of patent number 6,214,584 (described above in the Double Patenting rejections) because that patent is not claiming homologues of the IGIF protein, but is limited to the disclosed sequence, contiguous fragments thereof, and to variants differing by the substitution, addition, or deletion of a single amino acid.

### ***Conclusion***

28. The following prior art reference is made of record and considered pertinent to applicant's disclosure. However, while relevant it is not used as a basis for rejection for the stated reasons.

Okamura et al., IDS reference AX. This reference is found relevant in that it teaches an interferon- $\gamma$  inducing protein isolated from mice with a molecular weight of 18-18 kDa and an isoelectric point of 4.8. However, the reference is considered duplicative of U.S. Patent Number 5,912,324, issued to Okamura et al. These references are relevant as grounds for rejection only where the claims read on homologues to the human IGIF as the sequence of the murine IGIF disclosed by these reference would not render the human IGIF sequence obvious.

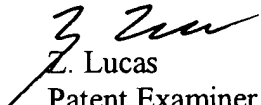
29. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 703-308-4240. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

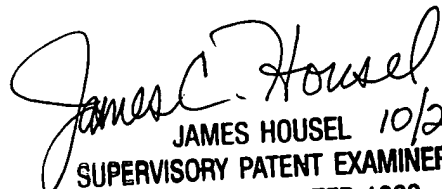
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the


Art Unit: 1648

organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Z. Lucas  
Patent Examiner  
October 18, 2002

  
JAMES HOUSEL 10/20/02  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

  
JASEMINE C. CHAMBERS  
DIRECTOR  
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